

April 18, 2008

Subject: Risk Assessment Evaluation of Breast Feeding Pathway

Brief Summary of Major Questions:

- (1) Portland Harbor Superfund Site- Should infant exposure from breastfeeding be included in the Portland Harbor Human Health Risk Assessment (HHRA)? If it is included, should this pathway be used to develop PRGs/RGs and what is the best forum for communicating the benefits of breastfeeding?
- (2) What methodology should be used to characterize risks for children consuming breast milk?
- (3) Should Region 10 EPA include this pathway of exposure in HHRA's for other sites (Superfund and RCRA) where mother's exposure to bioaccumulatives in sediment, soil, and other media could present a risk to breastfeeding infants? Is there any potential impact on other programs (e.g. WQC, MCLs)

(1) Pros and Cons for Inclusion of Breastfeeding in the Portland Harbor Human Health Risk Assessment (HHRA):

Pros:

- Breast feeding is a relevant exposure pathway at the Portland Harbor site, and at many other sites with bioaccumulating chemicals.
- There are reasonable risk assessment analytical tools to evaluate risks from breast feeding. EPA has guidance for evaluating this pathway in *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities* and it is included in EPA's 1997 *Exposure Factors Handbook* and the EPA's 2002 *Child-Specific Exposure Factors Handbook*. Region 10 (Dana Davoli and Marcia Bailey) has been discussing development of guidance for this pathway with Regions 1 and 2.
- This pathway has been included in the risk assessments for the GE/Housatonic River site, numerous evaluations of hazardous waste combustion facilities, including those in Region 10, and in EPA's draft dioxin reassessment document.
- For the Portland Harbor site, the highest calculated risks for PCBs would be from breast-feeding, so this pathway could become the most important for establishing preliminary cleanup levels for PCBs and possibly other bioaccumulatives.
- The importance of contaminants in breast milk has been recognized by public health professionals for years. The DHS fish advisory for the lower Willamette River already states that:
Women of childbearing age, particularly pregnant or breastfeeding women, should avoid eating resident fish from Portland Harbor, especially carp, bass and catfish.
Adding the breastfeeding scenario to the PH HHRA would provide quantitative support for this public health advisory.

- ODEQ is considering adding this scenario to their risk assessment guidance for multiple media under the State's Superfund law and to the ODEQ's *Guidance for Assessing Bioaccumulative Chemicals of Concern in Sediment* (April 2007). The ODEQ Director was briefed on this issue on April 18. OR DHS will likely issue a health consultation for nursing mothers for PH and possibly other sites (e.g., Bradford Island). OR DHS is expected to ask the OR legislature for money to conduct breast milk monitoring in OR.
- As a part of its PH Health Consultation, DHS would like to include a request asking the LWG to fund them to conduct a sustained community outreach campaign directed towards women of child-bearing age who are suspected high fish consumers in PH. Inclusion of this pathway in the PH RI would support the need for such as ~~request~~campaign.

Cons:

- The breast milk consumption exposure scenario is unlikely to drive cleanup levels. The final cleanup levels for chemicals such as PCBs, dioxins and DDT will likely be determined based on background levels, not risk-based levels. Driving the risk-based values lower will not advance our cleanup.
- Given the estimated risks from breastfeeding as well as the numerous benefits to both the child and mother, EPA would require the LWG to include in the HHRA language on the benefits associated with breast feeding and the need to follow the DHS fish advisory. We do not normally include benefit language in our HHRA's and have not done so for fish consumption.
- The current fish advisory already highlights pregnant and nursing mothers and we will need to rely on fish advisories as a component of our remedy. It may be more appropriate to handle this pathway through Oregon's Department of Human Services which is in a far better position than Superfund to present information about the risks and benefits associated with breast feeding broadly and working to educate the public about the risks and benefits associated consuming fish collected from Portland Harbor.
- We are in the final stages of negotiating the methodologies and assumptions for the PH HHRA and are to resolve outstanding issues by June 1. Although the breastfeeding scenario is included in the PH RI/FS Workplan, EPA has not provided the methodologies to be used to the LWG. This could be a very contentious issue as could the development of preliminary remedial goals and the request from DHS for outreach resources.
- If the breast milk pathway is added to the PH HHRA, it should be applicable to other hazardous waste sites in Region 10 (i.e., Superfund and RCRA) and could lead to questions for other programs (e.g. MCLs, AWQC)

Commented [DHS1]: I think it would be appropriate to mention here that such language was added to the HHRA for the Housatonic (i.e. there is a precedent).

(2) **Risk Assessment Methodology and Characterization of Risk:**

- Methodology for estimating a breastfeeding child's exposure for PH: calculate contaminant intake for a mother eating fish from PH; calculate the concentration of contaminant (e.g., PCBs) in breast-milk; calculate infant exposure assuming consumption of breast-milk.
- Selection of the appropriate averaging time and toxicity values has a fairly large impact on the exposure calculated for a breastfed child.
- Characterization of the impacts of this pathway can be done by either (1) comparing estimated exposures of breastfed infants at PH to those infants consuming breast milk with background levels of contaminants (Housatonic); (2) characterize risk using Superfund guidance, that is, calculate cancer risks and hazard quotients (Exposure Factors Handbook, Combustion Guidance), or (3) do both. **Attachment 1** provides a summary of the results using both methods.
- A draft memorandum has been prepared by Region 10 EPA, ODEQ and OR DHS that would direct the LWG on how to conduct a risk assessment for breast feeding and how to present the public health issue. A related health consultation is being reviewed at ATSDR headquarters.

(3) **Next Steps**

- Decision from Region 10 Superfund management as to whether the breast milk pathway should be included in the PH HHRA and in other Region 10 Superfund sites.
- Review of the PH draft memorandum on breastfeeding and of this issue summary memo by risk assessors, managers, and attorneys for both Superfund and RCRA. Technical review would also be requested from a small number of Regional risk assessors outside of Region 10 as well as a small number of EPA scientists from ORD.
- Submit PH draft memorandum to LWG.
- Decide if other Region 10 programs and the RA need to be included in these discussions.